

§ 285.3 Referencing NVLAP accreditation.

The term *NVLAP* (represented by the NVLAP logo) is a federally registered certification mark of the National Institute of Standards and Technology and the federal government, who retain exclusive rights to control the use thereof. Permission to use the term and/or logo is granted to NVLAP-accredited laboratories for the limited purposes of announcing their accredited status, and for use on reports that describe only testing and calibration within the scope of accreditation. NIST reserves the right to control the quality of the use of the term *NVLAP* and of the logo itself.

§ 285.4 Establishment of laboratory accreditation programs (LAPs) within NVLAP.

NVLAP establishes LAPs in response to legislative actions or to requests from private sector entities and government agencies. For legislatively mandated LAPs, NVLAP shall establish the LAP. For requests from private sector entities and government agencies, the Chief of NVLAP shall analyze each request, and after consultation with interested parties through public workshops and other means shall establish the requested LAP if the Chief of NVLAP determines there is need for the requested LAP.

§ 285.5 Termination of a LAP.

(a) The Chief of NVLAP may terminate a LAP when he/she determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Chief of NVLAP proposes to terminate a LAP, a notice will be published in the *FEDERAL REGISTER* setting forth the basis for that determination.

(b) When a LAP is terminated, NVLAP will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted shall remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP. Technical expertise will be maintained by NVLAP while any accreditation remains effective.

§ 285.6 Application for accreditation.

A laboratory may apply for accreditation in any of the established LAPs. The applicant laboratory shall provide a completed application to NVLAP, pay all required fees and agree to certain conditions as set forth in the NVLAP Application for Accreditation, and provide a quality manual to NVLAP (or a designated NVLAP assessor) prior to the assessment process.

§ 285.7 Assessment.

(a) *Frequency and scheduling.* Before initial accreditation, during the first renewal year, and every two years thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria.

(b) *Assessors.* NVLAP shall select qualified assessors to evaluate all information collected from an applicant laboratory pursuant to § 285.6 of this part and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(c) *Conduct of assessment.* (1) Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others.

(2) During the assessment, the assessor meets with management and laboratory personnel, examines the quality system, reviews staff information, examines equipment and facilities, observes demonstrations of testing or calibrations, and examines tests or calibration reports.

(3) The assessor reviews laboratory records including resumes, job descriptions of key personnel, training, and competency evaluations for all staff members who routinely perform, or affect the quality of the testing or calibration for which accreditation is sought. The assessor need not be given information which violates individual privacy, such as salary, medical information, or performance reviews outside the scope of the accreditation program. The staff information may be kept in the laboratory's official personnel folders or separate folders that contain only the information that the NVLAP assessor needs to review.

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(4) At the conclusion of the assessment, the assessor conducts an exit briefing to discuss observations and any deficiencies with the authorized representative who signed the NVLAP application and other responsible laboratory staff.

(d) *Assessment report.* At the exit briefing, the assessor submits a written report on the compliance of the laboratory with the accreditation requirements, together with the completed checklists, where appropriate.

(e) *Deficiency notification and resolution.* (1) Laboratories are informed of deficiencies during the on-site assessment, and deficiencies are documented in the assessment report (see paragraph (d) of this section).

(2) A laboratory shall, within thirty days of the date of the assessment report, provide documentation that the specified deficiencies have either been corrected and/or a plan of corrective actions as described in the NVLAP handbooks.

(3) If substantial deficiencies have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All deficiencies and resolutions will be subject to thorough review and evaluation prior to an accreditation decision.

(4) After the assessor submits their final report, NVLAP reviews the report and the laboratory's response to determine if the laboratory has met all of the on-site assessment requirements.

§ 285.8 Proficiency testing.

(a) NVLAP proficiency testing is consistent with the provisions contained in ISO/IEC Guide 43 (Parts 1 and 2), Proficiency testing by interlaboratory comparisons, where applicable, including revisions from time to time. Proficiency testing may be organized by NVLAP itself or a NVLAP-approved provider of services. Laboratories must participate in proficiency testing as specified for each LAP in the NVLAP program handbooks.

(b) *Analysis and reporting.* Proficiency testing data are analyzed by NVLAP and reports of the results are made known to the participants. Summary results are available upon request to other interested parties; e.g., profes-

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sional societies and standards writing bodies. The identity and performance of individual laboratories are kept confidential.

(c) *Proficiency testing deficiencies.* (1) Unsatisfactory participation in any NVLAP proficiency testing program is a technical deficiency which must be resolved in order to obtain initial accreditation or maintain accreditation.

(2) Proficiency testing deficiencies are defined as, but not limited to, one or more of the following:

(i) Failure to meet specified proficiency testing performance requirements prescribed by NVLAP;

(ii) Failure to participate in a regularly scheduled "round" of proficiency testing for which the laboratory has received instructions and/or materials;

(iii) Failure to submit laboratory control data as required; and

(iv) Failure to produce acceptable test or calibration results when using NIST Standard Reference Materials or special artifacts whose properties are well-characterized and known to NIST/NVLAP.

(3) NVLAP will notify the laboratory of proficiency testing deficiencies and actions to be taken to resolve the deficiencies. Denial or suspension of accreditation will result from failure to resolve deficiencies.

§ 285.9 Granting accreditation.

(a) The Chief of NVLAP is responsible for all NVLAP accreditation actions, including granting, denying, renewing, suspending, and revoking any NVLAP accreditation.

(b) Initial accreditation is granted when a laboratory has met all NVLAP requirements. One of four accreditation renewal dates (January 1, April 1, July 1, or October 1) is assigned to the laboratory and is usually retained as long as the laboratory remains in the program. Initial accreditation is granted for a period of one year; accreditation expires and is renewable on the assigned date.

(c) Renewal dates may be reassigned to provide benefits to the laboratory and/or NVLAP. If a renewal date is changed, the laboratory will be notified in writing of the change and any related adjustment in fees.